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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,533

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EXAMINER

CHANDRA, GYAN

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,533	Applicant(s) BEN-SASSON ET AL.	
	Examiner GYAN CHANDRA	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 18-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, drawn to a method for identifying candidate compounds for the modulation of signal transduction associated with a 7TM receptor.

Group 2, claim(s) 6, 14, 18, and 19, drawn to a compound identified by the method of claim 4 and a pharmaceutical composition thereof.

Group 3, claim(s) 7-8, and 32-34 drawn to a compound comprising at least a moiety for transport across cellular membrane and a pharmaceutical composition thereof.

Group 4, claim(s) 9-11, drawn to a method for the modulation of signal transduction associated with a 7TM receptor or treating a disease comprising administering a therapeutically effective amount of a compound of claim 6.

Group 5, claim(s) 12 and 13, drawn to a method of detecting a ligand that binds to a unique region of a 7TM receptor comprising providing a compound from Group 2, incubating with a sample for a time sufficient for said ligand to bind to said compound, and detecting any said ligand-said compound binding.

Group 6, claim(s) 20-26, drawn to a method for stimulating angiogenesis comprising contacting blood vessels with an effective amount of a compound.

Group 7, claim(s) 27-29, drawn to a method for the modulation of signal transduction associated with a 7TM receptor or treating a disease comprising administering a therapeutically effective amount of a compound of claim 7.

Group 8, claim(s) 30 and 31, drawn to a method of detecting a ligand that binds to a unique region of a 7TM receptor comprising providing a compound from Group 3,

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incubating with a sample for a time sufficient for said ligand to bind to said compound, and detecting any said ligand-said compound binding.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A. Group 1, recites the special technical feature of identifying candidate compounds for the modulation of signal transduction associated with a 7TM receptor, which is not required by the methods of Groups 1 and 4-8.

B. Group 2, recites the special technical feature of a compound identified by the method of claim 4 and a pharmaceutical composition thereof, which is not required by the product of Group 3.

C. Group 3, recites the special technical feature of a compound comprising at least a moiety for transport across cellular membrane and a pharmaceutical composition thereof, which is not required by the product of Group 2.

D. Group 4, recites the special technical feature of the modulation of signal transduction associated with a 7TM receptor or treating a disease comprising administering a therapeutically effective amount of a compound of claim 6, which is not required by methods of groups 1 and 5-8

E. Group 5, recites the special technical feature of detecting a ligand that binds to the unique region of a 7TM receptor comprising providing a compound from Group 2, incubating with a sample for a time sufficient for said ligand to bind to said compound, and detecting any said ligand-said compound binding, which is not required by methods of groups 1, and 4, 6-8.

F. Group 6, recites the special technical feature of stimulating angiogenesis comprising contacting blood vessels with an effective amount of a compound, which is not required by the methods of Groups 1, 4-5 and 7-8.

G. Group 7, recites the special technical feature of the modulation of signal transduction associated with a 7TM receptor or treating a disease comprising administering a therapeutically effective amount of a compound of claim 7, which is not required by the methods of Groups 1, 4-6 and 8.

H. Group 8, recites the special technical feature of detecting a ligand that binds to the unique region of a 7TM receptor comprising providing a compound from Group 3, incubating with a sample for a time sufficient for said ligand to bind to said compound, and detecting any said ligand-said compound binding, which is not required by the methods of Groups 1 and 4-7.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further Restriction within Group 6

Election of a compound: The special technical feature of Group 6 requires stimulation of angiogenesis comprising contacting blood vessels with an effective amount of a compound comprising a sequence (e.g., amino acids 135-154 of native EDG3, aa 143-151 of EDG3, aa 143-148 of EDG3, RooL103 as depicted in Fig. 1, R00L106 as depicted in Fig. 1).

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Each of the claimed sequences are composed of different amino acids and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching all of the above claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. Therefore, Applicant must choose 1 polypeptide sequence from the Group 6 against which the search should be performed.

Species Election for Groups 4 and 7

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 11, 26 and 29 are drawn to many patentably distinct species (e.g., hypertension, stroke, neurodegenerative diseases (including Alzheimer's disease), renal disease, psychiatric disease, cancer, asthma, coronary artery disease, arteriosclerosis diabetes..... and immunological disorders.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species and that each species is different from other species in its structure and function relationship such as stroke is very different than asthma, Alzheimer's disease or cancer. In addition, these species are not obvious variants of each other based on the current record.

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There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

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(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and (ii) the species to be examined even though the requirement may be traversed (37 CFR 1.143) and (iii) identification of the claims encompassing the elected invention and the elected species.

The election of an invention and the species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention and species.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

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Should applicant traverse on the ground that the inventions or the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions or the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant elects Group 6, a single amino acid sequence must be elected from the group to be considered fully responsive. If applicant elects a group from Group 4 or 7, one species from the disease group must be choose to be considered fully responsive. It noted that the election of a sequence for Group 6 is restriction election and a species election.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
06 October 2008
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647